

Application No. 09/560,046
Attorney's Docket No. 028870-224

REMARKS

Claims 1-12 and 15-37 are pending in the application. Claims 1, 18, 23 and 32 have been amended. Claim 1 has been amended to clarify that the composition comprises non-linked, small particles of bioactive glass in an amount effective to accelerate healing of wounds, accelerate healing of burns and/or improve the appearance of scar tissue resulting from a wound or burn, in a carrier. Support for this amendment may be found at least on page 4, line 17, page 17, line 18 and page 18, line 23. Claim 18 was amended to correct a typographical error. Claim 23 has been amended to place it in independent form in view of the allowance of this claim. Claim 23 has not been narrowed and was not amended for reasons related to statutory requirements. Claim 32 was amended to clarify that the composition comprises an antibacterially effective amount of non-linked, small particles of bioactive glass. Support for this amendment may be found at least on page 23, line 23. No new matter was added.

Claims 18-19 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. This rejection is moot in view of the amendment to claim 18.

Claims 8 and 34 were rejected under 35 U.S.C. § 101 as claiming the same invention as that of claims 1-2 of U.S. Patent No. 6,338,751. Applicants respectfully traverse this rejection.

According to the MPEP, in determining whether a statutory basis for a double patenting rejection exists, the question to be asked is: Is the same invention being claimed twice? A reliable test for double patenting under 35 U.S.C. § 101 is whether a claim in the application could be literally infringed without literally infringing a corresponding claim in the patent. *MPEP* § 804II.A.

Application No. 09/560,046
Attorney's Docket No. 028870-224

Claim 1 of the '751 patent provides a bioactive glass composition comprising particulate bioactive and biocompatible glass having a composition as defined and including particles less than 90 μm , wherein the particulate bioactive and biocompatible glass includes an effective dentin tubule occluding amount of particles less than about 2 μm . Claim 2 of the '751 patent provides a bioactive silica glass composition comprising particulate bioactive and biocompatible glass with a silica content of at least 40% and an effective dentin tubule occluding amount of particles less than about 5 microns wherein the bioactive glass comprises an effective amount of Ca and P to form hydroxyapatite in vivo.

Claim 8 of the present application is dependent on claim 1 and is directed to a composition comprising non-linked, small particles of bioactive glass in an amount effective to accelerate healing of wounds or burns and/or improve the appearance of scar tissue resulting from a wound or burn. Claim 34 is dependent on claim 32 and directed to an antibacterial composition comprising an antibacterially effective amount of non-linked, small particles of bioactive glass. The claims of the '751 patent are not directed to such compositions. Moreover, claims 8 and 34 do not have any feature regarding particle size. For at least these reasons, the claims in the application could be literally infringed without literally infringing any claim in the '751 patent and statutory double patenting does not exist. In view thereof, Applicants respectfully request that this rejection be withdrawn.

Claims 1-12, 15-17, 20 and 24-37 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 and 12 of U.S. Patent No. 5,834,008. Claims 1-12, 15-20 and 24-37 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,428,800. Claims 1, 7-9 and 32-35 were rejected under the judicially created

Application No. 09/560,046
Attorney's Docket No. 028870-224

doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,171,986. Each of these patents is commonly owned with the present application. Therefore, Applicants respectfully request that these rejections be withdrawn in view of the Terminal Disclaimer submitted herewith.

Claims 1-4, 7-8 and 32-34 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 5,972,384.¹ Applicants respectfully traverse this rejection.

Claim 1 of the '384 patent is directed to a particulate, biologically active, ceramic-glass matrix impregnated with one or more microencapsulated therapeutically beneficial drugs forming a ceramodrug matrix. Claim 1 of the present application is directed to a composition for the accelerated healing of wounds and burns and/or for improving the appearance of scar tissue resulting from such wounds and burns comprising non-linked, small particles of bioactive glass in an amount effective to accelerate healing of wounds or burns and/or improve the appearance of scar tissue resulting from a wound or burn, in a carrier. Nothing in the claims of the '384 patent describes or suggests a composition for accelerated healing of wounds and burns and/or for improving the appearance of scar tissue resulting from such wounds and burns. Additionally, nothing in the claims of the '384 patent describes or suggests a composition comprising non-linked, small particles of bioactive glass in an amount effective to accelerate healing of wounds or burns and/or improve the appearance of scar tissue resulting from a wound or burn.

¹ Applicants note that the '384 patent only has seven claims. Applicants additionally note that this patent issued from an application filed October 1, 1997, while the present application claims priority to an application filed September 19, 1996.

Application No. 09/560,046
Attorney's Docket No. 028870-224

Independent claim 32 is directed to an antibacterial composition comprising an antibacterially effective amount of non-linked, small particles of bioactive glass. As with the subject matter of claim 1, nothing in the claims of the '384 patent describes or suggests such a composition. In view thereof, Applicants respectfully request that this rejection be withdrawn.

Claims 1, 7, 9-10, 32-33 and 35-36 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2 and 16 of U.S. Patent No. 5,981,412. Applicants respectfully traverse this rejection.²

Claims 1 and 2 of the '412 patent relate to a bioactive ceramic composition defined therein. Claim 16 is directed to a reinforcement particulate. None of claims 1, 2 or 16 describe or suggest a composition for the accelerated healing of wounds and burns and/or for improving the appearance of scar tissue resulting from such wounds and burns. Additionally, nothing in the claims of the '412 patent describes or suggests a composition comprising non-linked, small particles of bioactive glass in an amount effective to accelerate healing of wounds or burns and/or improve the appearance of scar tissue resulting from a wound or burn.

Independent claim 32 is directed to an antibacterial composition comprising an antibacterially effective amount of non-linked, small particles of bioactive glass. As with the subject matter of claim 1, nothing in the claims of the '412 patent describes or suggests such a composition.

Applicants note the comment in the Office Action that it is the composition per se that is being examined, not how the composition will be

² Applicants note that this rejection appears improper in view of MPEP § 804, P. 800-19, which states that double patenting may exist between an issued patent and an application filed by the same inventive entity, or by an inventive entity having a common inventor with the patent and/or by the owner of the patent.

Application No. 09/560,046
Attorney's Docket No. 028870-224

subsequently used. However, the compositions as claimed define compositions comprising an amount of bioactive glass as defined in the claims effective for a particular purpose. This would not have been obvious from the '412 claims. In view thereof, Applicants respectfully request that this rejection be withdrawn.

Claims 1, 7, 9-10, 32-33 and 35-36 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2 of U.S. Patent No. 6,338,751. Applicants respectfully traverse this rejection.

As discussed above and in the Office Action, the claims of the '751 patent do not describe or suggest a composition for the accelerated healing of wounds and burns and/or for improving the appearance of scar tissue resulting from such wounds and burns. Additionally, nothing in the claims of the '751 patent describes or suggests a composition comprising non-linked, small particles of bioactive glass in an amount effective to accelerate healing of wounds or burns and/or improve the appearance of scar tissue resulting from a wound or burn.

Independent claim 32 is directed to an antibacterial composition comprising an antibacterially effective amount of non-linked, small particles of bioactive glass. As with the subject matter of claim 1, nothing in the claims of the '751 patent describes or suggests such a composition. In view thereof, Applicants respectfully request that this rejection be withdrawn.

Claims 1, 7, 8 and 32-34 were rejected under 35 U.S.C. § 102(e) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Hench et al., U.S. Patent No. 5,840,290. Applicants respectfully traverse this rejection.

Application No. 09/560,046
Attorney's Docket No. 028870-224

Hench is directed to an injectable bio-active glass in a dextran suspension for the repair of soft tissue or hard bone of mammals. Hench does not describe or suggest a composition for the accelerated healing of wounds and burns and/or for improving the appearance of scar tissue resulting from such wounds and burns. Additionally, nothing in the Hench patent describes or suggests a composition comprising non-linked, small particles of bioactive glass in an amount effective to accelerate healing of wounds or burns and/or improve the appearance of scar tissue resulting from a wound or burn.

Independent claim 32 is directed to an antibacterial composition comprising an antibacterially effective amount of non-linked, small particles of bioactive glass. As with the subject matter of claim 1, nothing in the Hench patent describes or suggests such a composition.

Applicants note the comment in the Office Action that it is the composition per se that is being examined, not how the composition will be subsequently used. However, the compositions as claimed comprise an amount of bioactive glass as defined effective for a particular purpose. This would not have been obvious from the Hench patent which describes fluid compositions of bio-active glass in aqueous solutions of dextrans. In view thereof, Applicants respectfully request that this rejection be withdrawn.

Claims 1, 7, 8 and 32-34 were rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Low, U.S. Patent No. 4,851,046. Applicants respectfully traverse this rejection.

Low is directed to periodontal osseous defect repair using a composition comprising particulate bioactive and biocompatible glass. Nothing in the Low patent describes or suggests a composition comprising

Application No. 09/560,046
Attorney's Docket No. 028870-224

non-linked, small particles of bioactive glass in an amount effective to accelerate healing of wounds or burns and/or improve the appearance of scar tissue resulting from a wound or burn.

Independent claim 32 is directed to an antibacterial composition comprising an antibacterially effective amount of non-linked, small particles of bioactive glass. As with the subject matter of claim 1, nothing in the Low patent describes or suggests such a composition. In view thereof, Applicants respectfully request that this rejection be withdrawn.

Applicants acknowledge with appreciation the allowance of claim 21-23. Applicants believe, in view of the foregoing, the remaining pending claims are now in condition for allowance.

Further and favorable action in the form of a Notice of Allowance is believed to be next in order, and such action is earnestly solicited. If there are any questions concerning this paper or the application in general, the Examiner is invited to telephone the undersigned.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

By: Mary B. Grant
Mary B. Grant
Registration No. 32,176

P.O. Box 1404
Alexandria, Virginia 22313-1404
(919) 941-9240
Date: February 6, 2003

I hereby certify that this correspondence is being filed by facsimile transmission to the Assistant Commissioner for Patents, Washington, D.C. 20231 to Facsimile Number 1.703.308.4556 on this date, February 6, 2003.

by Donnie S. Dietrich
Donnie S. Dietrich